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May 30, 2023

VIA CM/ECF

Peter R. Marksteiner
Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: *Baxalta Incorporated v. Genentech, Inc.*, No. 22-1461

Dear Colonel Marksteiner:

Pursuant to Federal Rule of Appellate Procedure 28(j), Appellant wishes to advise the Court that on May 18, 2023, the Supreme Court of the United States decided *Amgen Inc. v. Sanofi*, No. 21-757.

The *Amgen* record differs materially from the record here, and the decision confirms that summary judgment was improper.

Amgen claimed antibodies that "(1) bind to specific amino acids on a naturally occurring protein known as PCSK9, and (2) block PCSK9 from impairing the body's mechanism for removing LDL cholesterol from the bloodstream." Slip op. at 1. The claims cover "potentially millions [of] antibodies." *Id.* at 2. Identifying these antibodies required "painstaking experimentation" (*id.* at 17), and skilled artisans could not "do so reliably." *Id.* at 6. Amgen's approach was merely "trial-and-error." *Id.* at 16.

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The Supreme Court emphasized the narrowness of its decision: A specification is not "necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." *Id.* at 14. Indeed, "methods like a 'roadmap' . . . might suffice to enable other claims in other patents." Slip op. at 17.

Practicing the Baxalta claims at issue involves the reliability that was absent in *Amgen*. As in *In re Wands,* 858 F.2d 731 (Fed. Cir. 1988), which *Amgen* left undisturbed, the hybridoma-and-screening procedure does not involve undue experimentation and (when viewing facts in the light most favorable to Baxalta) has succeeded every time it has been attempted. *See* Reply Br. 4-12. No "trial-and-error" is involved. Reply Br. 6-8. Here, "screening is used only to identify **which** antibodies practice the claims, not **whether** any antibodies practice the claims." Reply Br. 4.

Baxalta's expert detailed the "critical differences between the claims at issue in *Amgen* and the claims at issue here." Appx19202; *see also* Appx19201-19204 (noting, *inter alia*, that practicing Amgen's claims was "unpredictable").

Moreover, in contrast to the "'vast' number of additional antibodies" claimed by Amgen, slip op. at 16, Baxalta's claims cover only a "focused and small" genus. Opening Br. 47.

The different record of this case should lead to a different result than *Amgen*.

Respectfully submitted,

/s/ William R. Peterson
William R. Peterson

Enclosure

potentially "open[ing] up new strategies for treating patients with haemophilia A and FVIII inhibitors."[210]

249. I disagree that the 2007 paper shows that the specification does not enable a POSITA to make and use the claimed invention. First, the 2007 article confirms that Dr. Scheiflinger et al. produced and identified procoagulant antibodies as taught and claimed in the '590 Patent: "We identified a series of antibodies specific for human FIX that mimicked the stimulatory effect of FVIIIa on FIXa. Upon binding to human FIXa, these antibodies enhanced the protease activity of FIXa towards its natural substrate FX about tenfold."[211]

250. Second, that the claimed invention could be used in certain therapeutic settings or to create future commercial embodiments (e.g., "a compound (an FIXa ligand) exhibiting FVIII-like activity that can be administered via a non-i.v. route"[212]) does not take away from a POSITA's ability to make and use the claimed invention, as taught in the specification.

251. Third, I understand Dr. Krishnaswamy to opine that any increase in procoagulant activity of FIXa would be therapeutically useful where even a slight increase in procoagulant activity has the potential to move a patient from one hemophilia A classification to another (e.g., move a patient from moderate to mild hemophilia A).

d. The specification and claim 1 of the '590 Patent differ significantly from the claims and specification at issue in *Amgen*.

252. Dr. Garcia opines that "[t]he '590 Patent has even less support and guidance than other patents that have been found to be invalid for lack of enablement," including the *Amgen* patents, and "[t]he disclosure supporting the functional limitations in Amgen's patent claims far

[210] Sheehan Rpt. ¶¶ 169-170.
[211] Ex. SS, Scheiflinger, et al., "Enhancement of the enzymatic activity of activated coagulation factor IX by anti-factor IX antibodies," J. Thromb. Haemost., 6:315-322 at 315 (2007).
[212] Ex. SS, Scheiflinger, et al., "Enhancement of the enzymatic activity of activated coagulation factor IX by anti-factor IX antibodies," J. Thromb. Haemost., 6:315-322 at 321 (2007).

exceeds the disclosure allegedly supporting claims 1-4, 19, and 20 of the '590 Patent."[213] According to Dr. Garcia, "[n]ot only were more representative species disclosed in Amgen's patents, but the claimed antibodies had relatively well-understood blocking functionality, as well as a clear screening method."[214] In Dr. Garcia's view, the '590 Patent "discloses fewer species for a broader genus of antibodies and antibody fragments, and claimed antibodies and antibody fragments must have an activation functionality, the mechanism for which is poorly understood, at best, without a clear screening method."[215]

253. I disagree with Dr. Garcia's comparison because it omits and does not take into account critical differences between the claims at issue in *Amgen* and the claims at issue here. The *Amgen* claims were directed to antibodies that bind to one or more of certain residues of the PCSK9 protein or bind an epitope on PCSK9 comprising certain residues and block PCSK9 from binding to LDL receptors.[216] As such, and unlike claim 1 of the '590 Patent that requires the antibodies simply bind to Factor IX or Factor IXa, the claims required antibodies that bind to PCSK9 at 15 specified residues out of 700 total residues or bind to an epitope on PCSK9 comprising certain of those 700 total residues.[217]

254. In addition, unlike the '590 Patent's specification that instructs a POSITA to undertake two key steps (e.g., producing antibodies using hybridoma or phage display techniques and screening antibodies using known, prior art assays), the *Amgen* patents' "roadmap" required several steps, including (i) making a known antibody binding D238; (ii) generating a pool of

[213] Garcia Rpt. ¶¶ 222, 228; *see also id.* at ¶¶ 223-227.
[214] *Id.* at ¶ 228.
[215] *Id.*
[216] 987 F.3d at 1083.
[217] *Id.*; *Amgen, Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 4058927 at *10-*11 (D. Del. Aug. 28, 2019); Ex. GGGG, Trial Tr. Vol. III at 624:22-625:8, 629:8-18.

antibodies through super immunization procedure and testing the pool of antibodies to bind PCSK9; (iii) running a binning assay against the known antibody to identify competing antibodies; (iv) running a blocking assay to determine whether the antibodies block the binding of PCSK9 to the LDL receptor; and (v) verifying the identity of the amino acids bound by alanine or arginine scanning.[218]

255. Moreover, the lead inventor of the Amgen patents testified that he took similar steps to obtain the claimed antibodies in the first instance.[219] The significant similarity between the "roadmap" and the inventor's steps to discover the disclosed antibodies showed that attempting to obtain a claimed antibody not yet disclosed or a variant of a disclosed antibody would require "essentially the same amount of work as the inventors of the patents-in-suit" did to discover the invention.[220] In contrast, as discussed above, a POSITA could use Examples 1 and 2 in the '590 Patent to make and use the claimed invention without resorting to the same, initial experimentation the inventors undertook or otherwise starting from scratch.

256. Even after producing antibodies using hybridoma techniques, a POSITA in *Amgen* still would not know the region on PCSK9's surface having a unique structure and chemical properties where PCSK9 binds to LDL receptors.[221] Knowing that information was critical to enablement of the *Amgen* claims because, as discussed above, the claims required that the

[218] 987 F.3d at 1085; *Amgen, Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 4058927, at *10-*11 (D. Del. Aug. 28, 2019).
[219] *Amgen, Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 4058927, at *10-*12 (D. Del. Aug. 28, 2019).
[220] *Id.* at *11-*12.
[221] *See, e.g.*, *Amgen, Inc. v. Sanofi*, No. 14-1317-RGA, 2019 WL 4058927, at *8, *10-*12 (D. Del. Aug. 28, 2019); *Amgen, Inc. v. Sanofi*, No. 14-1317-RGA, 227 F.Supp.3d 333 at 342-44 (D. Del. Jan. 3, 2017).

antibodies to PCSK9 bind one or more of 15 out of 700 total residues in PCSK9.[222] It is that particular requirement that made generating antibodies to bind to specific residues so unpredictable. The '590 Patent's claim 1, in contrast, merely required binding to Factor IX or Factor IXa; it does not require binding to specific residues with Factor IX or Factor IXa. And, as discussed above, conventional hybridoma and phage display techniques would inevitably produce antibodies that bind to Factor IX/Factor IXa.

257. Further, unlike the '590 Patent's routine screening using a chromogenic assay, which allows a POSITA to confirm binding and assess an increase in procoagulant activity, the hybridoma cell lines in Amgen's patents were screened using ELISA optical density measurements to identify hybridoma cell lines that produce antibodies (i) specific to PCSK9 (*see, e.g.*, Example 3, "Primary Screen" and "Confirmatory Screen"), (ii) capable of binding to both human and mouse PCSK9 (*see, e.g.*, Example 3, "Mouse Cross-Reactivity Screen"), (iii) capable of binding D374Y mutant PCSK9 (*see, e.g.*, Example 3, "D374Y Mutant Binding Screen"), and (iv) that block PCSK9 – LDLR binding (*see, e.g.*, Example 3, "Large Scale Receptor Ligand Blocking Screen" and "Receptor Ligand Binding Assay on Blocker Subset").[223]

258. For at least these reasons, I disagree with Dr. Garcia that "[i]f Amgen's patents lack enablement, then the asserted claims of the '590 Patent, with far broader scope and far less guidance, lack enablement as well."[224]

2. The nature of the invention and the breadth of the claims.

259. The '590 Patent is directed to antibodies that bind to Factor IX/Factor IXa and increase the procoagulant activity of Factor IXa. An object of the invention is to treat patients

[222] *See, e.g.*, Ex. GGGG, Trial Tr. Vol. III at 624:22-625:8, 629:8-18; *Amgen*, 987 F.3d 1080 at 1083.
[223] Ex. TT, U.S. Patent No. 8,829,165 at 77:20-81:34 (Example 3).
[224] Garcia Rpt. ¶ 228.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

AMGEN INC. ET AL. *v.* SANOFI ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 21–757. Argued March 27, 2023—Decided May 18, 2023

This case concerns patents covering antibodies engineered by scientists that help reduce levels of low-density lipoprotein (LDL) cholesterol, sometimes called bad cholesterol because it can lead to cardiovascular disease, heart attacks, and strokes. To treat patients with high LDL cholesterol, scientists explored how antibodies might be used to inhibit PCSK9—a naturally occurring protein that binds to and degrades LDL receptors responsible for extracting LDL cholesterol from the bloodstream. Two pharmaceutical companies—Amgen and Sanofi—each developed a PCSK9-inhibiting drug. In 2011, Amgen obtained a patent for the antibody employed in its drug, and Sanofi received one covering the antibody used in its drug. Each patent describes the relevant antibody by its unique amino acid sequence. The dispute in this case concerns two additional patents Amgen obtained in 2014 that relate back to the company's 2011 patent. These later-issued patents purport to claim for Amgen "the entire genus" of antibodies that (1) "bind to specific amino acid residues on PCSK9," and (2) "block PCSK9 from binding to [LDL receptors]." 872 F. 3d 1367, 1372. As part of its submission to the patent office, Amgen identified the amino acid sequences of 26 antibodies that perform these two functions. Amgen then described two methods—one Amgen called "the roadmap" and a second it called "conservative substitution"—that scientists could use to make other antibodies that perform the binding-and-blocking functions described in the claims.

After Amgen obtained the 2014 patents, it sued Sanofi for infringement. Sanofi replied that it was not liable to Amgen for infringement because Amgen's relevant claims were invalid under the Patent Act's "enablement" requirement. That provision requires a patent applicant to describe the invention "in such full, clear, concise, and exact terms

as to enable any person skilled in the art . . . to make and use the [invention]." 35 U. S. C. §112(a). Sanofi characterized the methods Amgen outlined for generating additional antibodies as amounting to little more than a trial-and-error process of discovery, and thus contended that Amgen's patents failed to meet the enablement requirement because they sought to claim for Amgen's exclusive use potentially millions more antibodies than the company had taught persons skilled in the art to make. Both the district court and the Federal Circuit sided with Sanofi.

Held: The courts below correctly concluded that Amgen failed "to enable any person skilled in the art . . . to make and use the [invention]" as defined by the relevant claims. Pp. 7–19.

(a) The patent "bargain" describes the exchange that takes place when an inventor receives a limited term of "protection from competitive exploitation" in exchange for bringing "new designs and technologies into the public domain through disclosure" for the benefit of all. *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.,* 489 U. S. 141, 150. From the Patent Act's beginnings, Congress has sought to ensure the benefit of this bargain for the public by requiring the patent applicant to deposit a "specification . . . so particular . . . as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same." 1 Stat. 110. Over time, Congress has left this "enablement" obligation largely intact.

This Court has addressed the enablement requirement many times, and its decisions in *O'Reilly* v. *Morse,* 15 How. 62, *The Incandescent Lamp Patent,* 159 U. S. 465, and *Holland Furniture Co.* v. *Perkins Glue Co.,* 277 U. S. 245, reinforce the simple statutory command: If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In *Morse*, for example, the Court held that one of the claims in Morse's patent for a telegraphic system was "too broad, and not warranted by law." 15 How., at 113. The problem was that the claim covered *all* means of achieving telegraphic communication, yet Morse's specification did not describe how to make or use them all. See *id.,* at 113–117. In *Incandescent Lamp*, inventors of an "electric lamp" with an "incandescing conductor" made of "carbonized paper" claimed that a lamp created by Thomas Edison infringed their patent because it used bamboo as a conductor. The Court sided with Edison because the rival inventors, rather than confining their claim to carbonized paper, "made a broad claim for every fibrous and textile material." 159 U. S., at 472. That broad claim "might" have been permissible, the Court allowed, if the

inventors had disclosed "a quality common" to fibrous and textile substances that made them "peculiarly" adapted to incandescent lighting, but they did not. *Ibid.* Finally, in *Holland Furniture*, a company that had developed a starch glue that was similar enough to animal glue to be used for wood veneering included a claim in its patent covering all "starch glue which, [when] combined with about three parts or less . . . of water, will have substantially the same properties as animal glue." 277 U. S., at 251. The specification described the key input—the "starch ingredient"—in terms of its "use or function" rather than its "physical characteristics or chemical properties." *Id.,* at 256. The problem, as the Court put it, was that "[o]ne attempting to use or avoid the use of [the] discovery as so claimed and described functionally could do so only after elaborate experimentation" with different starches. *Id.*, at 257.

All this is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. It may suffice to give an example if the specification also discloses "some general quality . . . running through" the class that gives it "a peculiar fitness for the particular purpose." *Incandescent Lamp*, 159 U. S., at 475. Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing. See, *e.g., Wood* v. *Underhill*, 5 How. 1, 4–5. A specification may call for a reasonable amount of experimentation to make and use a claimed invention, and reasonableness in any case will depend on the nature of the invention and the underlying art. See *Minerals Separation, Ltd.* v. *Hyde,* 242 U. S. 261, 270–271. Pp. 7–15.

(b) Turning to the patent claims at issue in this case, Amgen's claims sweep much broader than the 26 exemplary antibodies it identifies by their amino acid sequences. Amgen has failed to enable all that it has claimed, even allowing for a reasonable degree of experimentation. Amgen's claims bear more than a passing resemblance to the broadest claims in *Morse*, *Incandescent Lamp*, and *Holland Furniture*. While Amgen seeks to monopolize an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors—the record reflects that this class of antibodies does not include just the 26 that Amgen has described by their amino acid sequences, but a vast number of additional antibodies that it has not.

Amgen insists that its claims are nevertheless enabled because scientists can make and use every functional antibody if they simply follow the "roadmap" or "conservative substitution." These two approaches, however, amount to little more than two research assignments. The "roadmap" merely describes step-by-step Amgen's own trial-and-error method for finding functional antibodies. Not

much different, "conservative substitution" requires scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too.

Amgen's alternative arguments lack merit. Amgen first suggests that the Federal Circuit erred by conflating the question whether an invention is enabled with the question how long may it take a person skilled in the art to make every embodiment within a broad claim. But the Federal Circuit made clear that it was not treating as dispositive the cumulative time and effort required to make the entire class of antibodies. Amgen next argues that the Patent Act supplies a single, universal enablement standard, while the Federal Circuit applied a higher standard to Amgen's claims that encompass an entire genus of embodiments defined by their function. The Court agrees in principle that there is one statutory enablement standard, but the Federal Circuit's treatment in this case is entirely consistent with Congress's directive and this Court's precedents. Finally, while Amgen warns that a ruling against it risks destroying the incentives that lead to breakthrough inventions, since 1790 Congress has included an enablement mandate as one feature among many designed to achieve the balance it wishes to strike between incentivizing inventors and ensuring the public receives the full benefit of their innovations. In this case, the Court's duty is to enforce the statutory enablement requirement according to its terms. Pp. 15–19.

10 F. 4th 1016, affirmed.

GORSUCH, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 21–757

AMGEN INC., ET AL., PETITIONERS *v.* SANOFI, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[May 18, 2023]

JUSTICE GORSUCH delivered the opinion of the Court.

The development of antibody drugs has yielded life-changing therapies. Individuals across the world now rely on antibody drugs to treat conditions ranging from Crohn's disease to cancer. This case concerns patents covering antibodies that help reduce levels of low-density lipoprotein cholesterol, sometimes called LDL cholesterol (for the obvious reason) or bad cholesterol (because it can lead to cardiovascular disease, heart attacks, and strokes).

The case comes to us this way. Several years ago, petitioners (Amgen) obtained two patents. Together, these patents claim a monopoly over all antibodies that (1) bind to specific amino acids on a naturally occurring protein known as PCSK9, and (2) block PCSK9 from impairing the body's mechanism for removing LDL cholesterol from the bloodstream. Soon after receiving these patents, Amgen sued respondents (Sanofi) for infringement. In response, Sanofi argued that the patents were invalid under §112 of the Patent Act. That provision requires a patent applicant to describe its invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the [invention]." 35 U. S. C. §112(a). Sanofi contended that

Amgen's patents failed to meet this standard because they sought to claim for Amgen's exclusive use potentially millions more antibodies than the company had taught scientists to make. In the end, both the district court and Federal Circuit sided with Sanofi. The question we face is whether to disturb their judgment.

I

A

The immune system produces antibodies as a defense to foreign agents called antigens. When a particular antigen—a virus, for example—enters the body, the immune system generates antibodies to attack it. In a successful attack, the antibodies target and bind to the antigen, stopping it from causing harm to the body. See Brief for Sir Gregory Paul Winter et al. as *Amici Curiae* 8 (Winter Brief); M. Lemley & J. Sherkow, The Antibody Patent Paradox, 132 Yale L. J. 994, 1001–1002 (2023).

Antibodies are incredibly diverse. Some scientists estimate that there may be as many unique antibodies as there are stars in the galaxy. See *id.,* at 1003; see also B. Briney, A. Inderbitzin, C. Joyce, & D. Burton, Commonality Despite Exceptional Diversity in the Baseline Human Antibody Repertoire, 566 Nature 393, 397 (No. 7744, Feb. 2019) (estimating that the immune system could potentially generate up to a quintillion unique antibodies). This diversity shows up in both structure and function.

Start with structure. "When scientists refer to an antibody's 'structure,'" they may have in mind "several related concepts," each of which describes "what an antibody *is*." Winter Brief 10. Antibodies are made up of amino acids, and scientists commonly identify a particular antibody according to its specific sequence of amino acids—what they call an antibody's "'primary structure.'" *Id.*, at 9–10. But antibodies are not just linear chains of amino acids. As the

atoms of the amino acids interact with each other, they create folds that result in complex three-dimensional shapes. *Ibid.* Scientists refer to an antibody's intricate topography as its "tertiary structure." *Id.*, at 10.

An antibody's structure does much to dictate its function—its ability to bind to an antigen and, in some instances, to block other molecules in the body from doing the same. "For an antibody to bind to an antigen, the two surfaces have to fit together and contact each other at multiple points." *Id.*, at 11. But just because an antibody can bind to an antigen does not mean that it can also block. To bind and block, the antibody must establish a sufficiently broad, strong, and stable bond to the antigen. See *ibid.* Different antibodies have different binding and blocking capacities based on the amino acids that compose them and their three-dimensional shapes. See *id.*, at 11–12.

Despite recent advances, aspects of antibody science remain unpredictable. For example, scientists understand that changing even one amino acid in the sequence can alter an antibody's structure and function. See *id.*, at 14. But scientists cannot always accurately predict exactly how trading one amino acid for another will affect an antibody's structure and function. *Ibid.* As Amgen's expert testified at trial: "'[T]he way in which you get from sequence to that three-dimensional structure isn't fully understood today. It's going to get a Nobel Prize for somebody at some point, but translating that sequence into a known three-dimensional structure is still not possible.'" *Id.*, at 14–15.

B

While the immune system naturally produces an army of antibodies to protect us from various harms, scientists are now able to engineer antibodies to assist in treating diseases. Some of these lab-made antibodies target not foreign agents but the body's own proteins, receptors, and ligands. "While naturally occurring in our bodies, these [proteins,

receptors, and ligands] can also be involved in inflammatory disorders, uncontrolled cell growth, or other biological pathways that may be associated with disease." *Id.*, at 8.

One part of this effort has focused on the creation of antibodies to treat patients with high LDL cholesterol. A silent killer, LDL cholesterol can contribute to the formation of plaque in the arteries that may lead to cardiovascular disease, heart attacks, and strokes. For many people with high LDL cholesterol, drugs called statins offer an effective treatment. For others, statins do not work well or come with unwelcome side effects. In those cases, a relatively new antibody-based treatment known as a PCSK9 inhibitor may be appropriate. See *Amgen Inc.* v. *Sanofi*, 872 F. 3d 1367, 1371 (CA Fed. 2017).

PCSK9 is a naturally occurring protein that binds to and degrades LDL receptors. That can pose a problem because the body produces LDL receptors to perform the beneficial function of extracting LDL cholesterol from the bloodstream. See *ibid.* Scientists have understood this much for some time. But it wasn't until fairly recently that they began exploring how antibodies might be used to inhibit PCSK9 from binding to and degrading LDL receptors as a way to treat patients with high LDL cholesterol.

In the mid-2000s, a number of pharmaceutical companies began looking into the possibility of making antibodies to target PCSK9. See Brief for Respondents 7; Brief for Arnold Ventures et al. as *Amici Curiae* 17–20. More precisely, they sought to create antibodies that could bind to a particular region of PCSK9 called the "sweet spot." See Brief for Petitioners 10–11. The sweet spot is a sequence of 15 amino acids out of PCSK9's 692 total amino acids. *Id.*, at 11. By binding to the sweet spot, scientists found, an antibody could prevent PCSK9 from binding to and degrading LDL receptors. See *id.*, at 10–11; *Amgen*, 872 F. 3d, at 1371.

Eventually, Amgen developed a PCSK9-inhibiting drug

that it marketed under the name Repatha, and Sanofi produced one it labeled Praluent. Each drug employs a distinct antibody with its own unique amino acid sequence. See *id.,* at 1371–1372; Brief for Respondents 8–10. In 2011, Amgen obtained a patent for the antibody employed in Repatha, and Sanofi received one covering the antibody used in Praluent. See *id.,* at 8, 9. Each patent describes the relevant antibody by its amino acid sequence. See *ibid.* Neither of these patents is at issue in this case.

Instead, our dispute focuses on two additional patents Amgen obtained in 2014 that relate back to the company's 2011 patent. See U. S. Patent No. 8,829,165 (Sept. 9, 2014); U. S. Patent No. 8,859,741 (Oct. 14, 2014). We refer to them as the '165 and '741 patents. In particular, this case revolves around claims 19 and 29 of the '165 patent and claim 7 of the '741 patent. See 987 F. 3d 1080, 1082 (CA Fed. 2021). In these claims, Amgen did not seek protection for any particular antibody described by amino acid sequence. Instead, Amgen purported to claim for itself "the entire genus" of antibodies that (1) "bind to specific amino acid residues on PCSK9," and (2) "block PCSK9 from binding to [LDL receptors]." *Amgen*, 872 F. 3d, at 1372.

As part of its submission to the patent office, Amgen identified the amino acid sequences of 26 antibodies that perform these two functions, and it depicted the three-dimensional structures of two of these 26 antibodies. 987 F. 3d, at 1083. But beyond that, Amgen only offered scientists two methods to make other antibodies that perform the binding and blocking functions it described. The first method is what Amgen calls the "roadmap." Brief for Petitioners 13. At a high level, the roadmap directs scientists to: (1) generate a range of antibodies in the lab; (2) test those antibodies to determine whether any bind to PCSK9; (3) test those antibodies that bind to PCSK9 to determine whether any bind to the sweet spot as described in the claims; and (4) test those antibodies that bind to the sweet spot as described in

the claims to determine whether any block PCSK9 from binding to LDL receptors. See *id.*, at 13–14. The second method is what Amgen calls "conservative substitution." *Id.*, at 14, 17. This technique requires scientists to: (1) start with an antibody known to perform the described functions; (2) replace select amino acids in the antibody with other amino acids known to have similar properties; and (3) test the resulting antibody to see if it also performs the described functions. See *id.*, at 14–15.

C

Soon after receiving the '165 and '741 patents, Amgen sued Sanofi for infringing them. Sanofi replied that it was not liable to Amgen because the relevant claims were invalid as a matter of law. Invalid, Sanofi said, because Amgen had not enabled a person skilled in the art to make and use all of the antibodies that perform the two functions Amgen described in its claims. See 987 F. 3d, at 1083–1085. While Amgen had identified the amino acid sequences of 26 antibodies that bind to PCSK9 and block it from binding to LDL receptors, Sanofi observed that Amgen's claims cover potentially millions more undisclosed antibodies that perform these same functions. And, Sanofi argued, neither of the two methods Amgen had outlined for generating additional antibodies with the same functions enable a person skilled in the art to do so reliably. Instead, Sanofi submitted, those methods require scientists to engage in little more than a trial-and-error process of discovery. See *id.*, at 1085.

After lengthy proceedings, the district court granted Sanofi judgment as a matter of law, concluding that the claims at issue "are not enabled." 2019 WL 4058927, *13 (Del., Aug. 28, 2019). The Federal Circuit affirmed. 987 F. 3d, at 1088. It determined that "no reasonable factfinder could conclude" that Amgen had provided "adequate guidance" to make and use the claimed antibodies "beyond the narrow scope of the [26] working examples" it had identified

by their amino acid sequences. *Ibid.* In response to Amgen's petition for certiorari, we agreed to take up the case. 598 U. S. ___ (2022).

II

The Constitution vests Congress with the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Art. I, §8, cl. 8. Right there in the text, one finds the outline of what this Court has called the patent "bargain." *Bonito Boats*, *Inc.* v. *Thunder Craft Boats*, *Inc.*, 489 U. S. 141, 150 (1989). In exchange for bringing "new designs and technologies into the public domain through disclosure," so they may benefit all, an inventor receives a limited term of "protection from competitive exploitation." *Id.*, at 151; see also The Federalist No. 43, p. 272 (C. Rossiter ed. 1961) (J. Madison) (explaining that in such cases "[t]he public good fully coincides . . . with the claims of individuals").

Congress has exercised this authority from the start. The Patent Act of 1790 promised up to a 14-year monopoly to any applicant who "invented or discovered any useful art, manufacture, . . . or device, or any improvement therein not before known or used." Act of Apr. 10, 1790, §1, 1 Stat. 110. Reflecting the *quid-pro-quo* premise of patent law, the statute required the applicant to deposit with the Secretary of State a "specification . . . so particular . . . as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same." §2, *ibid.* The statute made clear that this disclosure would ensure "the public may have the full benefit [of the invention or discovery], after the expiration of the patent term." *Ibid.*

Even as Congress has revised the patent laws over time, it has left this "enablement" obligation largely intact. See

35 U. S. C. §§111, 112. Section 111 of the current Patent Act provides that a patent application "shall include . . . a specification as prescribed by section 112." §111(a)(2)(A). Section 112, in turn, requires a specification to include "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." §112(a). So today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, "upon the expiration of [the patent], the knowledge of the invention [i]nures to the people, who are thus enabled without restriction to practice it." *United States* v. *Dubilier Condenser Corp.*, 289 U. S. 178, 187 (1933); see also *Grant* v. *Raymond*, 6 Pet. 218, 247 (1832) (Marshall, C. J.) ("This is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue a patent."); *Whittemore* v. *Cutter*, 29 F. Cas. 1120, 1122 (No. 17,600) (CC Mass. 1813) (Story, J.) ("If therefore [the disclosure] be so obscure, loose, and imperfect, that this cannot be done, it is defrauding the public of all the consideration, upon which the monopoly is granted.").

This Court has addressed the enablement requirement on many prior occasions. See, *e.g.*, *Wood* v. *Underhill*, 5 How. 1 (1846); *O'Reilly* v. *Morse*, 15 How. 62 (1854); *The Incandescent Lamp Patent*, 159 U. S. 465 (1895); *Minerals Separation, Ltd.* v. *Hyde*, 242 U. S. 261 (1916); *Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U. S. 245 (1928). While the technologies in these older cases may seem a world away from the antibody treatments of today, the decisions are no less instructive for it.

Begin with *Morse*. While crossing the Atlantic Ocean in 1832 aboard a ship named *Sully*, Samuel Morse found himself in conversation with other passengers about "experiments and discoveries" around electromagnetism. 15 How.,

at 68. "In the course of this discussion, it occurred to [Morse] that, by means of electricity, signs representing figures, letters, or words, might be legibly written down at any distance." *Id.*, at 69. So clear was the idea in Morse's mind that, "[b]efore he landed in the United States, he had . . . drawn out in his sketch book . . . the form of an instrument for an electro-magnetic telegraph." *Ibid.*

Immediately upon his arrival in New York, Morse showed his brothers his sketches. See *id.*, at 69–70. He spent the next few years refining his invention. See *id.*, at 70–76. The "great difficulty" he faced was that "the galvanic current, however strong in the beginning, became gradually weaker as it advanced on the wire[,] and was not strong enough to produce a mechanical effect, after a certain distance." *Id.*, at 107. By 1837, Morse had a solution: "combining two or more electric or galvanic circuits, with independent batteries for the purpose of overcoming the diminished force of electro-magnetism in long circuits." *Id.*, at 109. Morse demonstrated his telegraph the following year at the Franklin Institute in Philadelphia, and he displayed it soon after in Congress. See *id.*, at 76. He received a patent in 1840, which reissued in 1848. See *id.*, at 81–83.

The litigation that brought Morse before this Court concerned a telegraphic system that Henry O'Reilly had installed between Louisville and Nashville. See *id.*, at 65. Morse sued O'Reilly for infringement, alleging that O'Reilly's system was "identical with" Morse's own. *Id.*, at 66. O'Reilly mounted a number of defenses, including that Morse's patent was void because it lacked an adequate specification. See *id.*, at 99–101, 112.

Morse's patent included eight claims, and this Court had no trouble upholding seven of them—those limited to the telegraphic structures and systems he had designed. See *id.*, at 85–86, 112, 117. But the Court paused on the eighth. That claim covered "the essence" of the invention, which

Morse described as "the use of the motive power of the electric or galvanic current . . . however developed for marking or printing intelligible characters, signs, or letters, at any distances." *Id.*, at 112 (internal quotation marks omitted). Leaving no doubt about this claim's scope, Morse stated plainly: "'I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims.'" *Ibid.*

The Court held the eighth claim "too broad, and not warranted by law." *Id.*, at 113. The problem was that it covered *all* means of achieving telegraphic communication, yet Morse had not described how to make and use them all. See *id.*, at 113–117; see also 3 Chisum on Patents §7.03[1], pp. 7–18 to 7–19 (2021). "[I]f the eighth claim . . . can be maintained," the Court concluded, "there was no necessity for any specification, further than to say that he had discovered that, by using the motive power of electro-magnetism, he could print intelligible characters at any distance." 15 How., at 119. "[I]t will be admitted on all hands, that no patent could have issued on such a specification." *Ibid.*

Consider, too, *Incandescent Lamp*. For much of the 19th century, gas lamps helped illuminate streets and supplemented candles inside homes, factories, offices, and theaters. But gas lighting had drawbacks. It took effort to ignite lamps each night and extinguish them each morning. Then there were the problems of soot and fumes. See R. Stross, The Wizard of Menlo Park 84–85 (2007) (Stross). By the 1870s, many had experimented with other forms of lighting, including incandescence and the arc light. 159 U. S., at 470. But these alternatives burned unreliably or with unbearable brightness. See *id.*, at 470–471. The latter problem in particular led one observer to lament this "new sort of urban star," which shines "horrible, unearthly, obnoxious" light. R. L. Stevenson, A Plea for Gas Lamps, in Virginibus Puerisque and Other Papers 295 (1881).

Enter Thomas Edison. From his laboratory in Menlo

Park, Edison and a team toiled to improve upon the prevailing method of incandescent lighting, which tended to employ carbon filaments. 159 U. S., at 471–473. The problem with carbon filaments was that they disintegrated rapidly. In a sense, "carbon contained in itself the elements of its own destruction." *Id.*, at 471. Seeking an alternative, Edison tinkered for a time with platinum, but it was expensive and difficult to bring to the point of incandescence without melting. Stross 78, 82. Eventually, Edison dispatched men across the globe to collect specimens of bamboo. *Id.*, at 109–110. One sample from Japan worked brilliantly because "[its] fibres [ran] more nearly parallel than in other species of wood." 159 U. S., at 473. Satisfied, Edison arranged to have a Japanese farmer supply all of the bamboo he would ever need. Stross 110.

But there was a catch. William Sawyer and Albon Man had obtained a patent for an "'electric lamp'" with an "'incandescing conductor'" made of "'carbonized fibrous or textile material,'" which they claimed was an improvement over conductors made of "'mineral or gas carbon.'" 159 U. S., at 466, 468. Sawyer and Man's patent had not won them commercial success. They had designed a lamp with a conductor made of carbonized paper, but the lamp proved defective and quickly fell out of use. See *id.*, at 471–472. Still, their failure did not stop them from seeking to share in some of Edison's success. Sawyer and Man alleged that Edison's lamp infringed their patent because it "made use of a fibrous or textile material, covered by the patent." *Id.*, at 471. What was that offending material? Bamboo.

This Court sided with Edison. It held that Sawyer and Man's patent claimed much but enabled little. "Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor." *Id.*, at 472. But "[i]nstead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous and

textile material." *Ibid.* Even that broad claim "might" have been permissible, the Court allowed, if Sawyer and Man had disclosed "a quality common" to fibrous and textile substances that made them "peculiarly" adapted to incandescent lighting. *Ibid.* Had they done so, others would have known how to select among such materials to make an operable lamp. But the record showed that most fibrous and textile materials failed to work. Only through "painstaking experimentation" did Edison discover that bamboo "answered the required purpose." *Id.*, at 475–476. The Court summed up things this way: "[T]he fact that paper happens to belong to the fibrous kingdom did not invest [Sawyer and Man] with sovereignty over this entire kingdom." *Id.*, at 476.

The Court returned to these principles in *Holland Furniture*. There, the evidence indicated that animal glue has properties that have long made it excellent for wood veneering. See 277 U. S., at 247. Seeking a substitute, Perkins Glue Company had developed and patented a starch glue similar enough to animal glue that craftsmen could also use it for wood veneering. See *ibid.* Yet Perkins's patent included a claim that went beyond the specific starch glue it manufactured. See *id.*, at 250–251. This claim covered all "starch glue which, [when] combined with about three parts or less by weight of water, will have substantially the same properties as animal glue." *Id.*, at 251. Perkins's specification instructed gluemakers to choose a "starch ingredient" with "such qualities" that it would yield a product "'as good as animal glue'" for wood veneering "when combined with three parts of water and with alkali." *Id.*, at 256.

The Court held this broad claim invalid for lack of enablement. *Id.*, at 258. The specification described the key input—the "starch ingredient"—in terms of its "use or function" rather than its "physical characteristics or chemical properties." *Id.*, 256. And that left gluemakers in a bind. As the Court put it: "One attempting to use or avoid the

use of Perkins' discovery as so claimed and described functionally could do so only after elaborate experimentation" with different starches. *Id.*, at 257. To be sure, the Court held, Perkins was entitled to its patent on the specific starch glue it had invented. See *id.*, at 255. The specification described that glue's "characteristic ingredient" with "particularity." *Ibid.* But just as Morse could not claim all means of telegraphic communication, and Sawyer and Man could not claim all fibrous and textile materials for incandescence, Perkins could not claim all starch glues made from whatever starch happened to perform as well as animal glue. To hold otherwise, the Court said, "would extend the monopoly beyond the invention." *Id.*, at 258.

Our decisions in *Morse*, *Incandescent Lamp*, and *Holland Furniture* reinforce the simple statutory command. If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable. See §112(a); see also *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U. S. 405, 419 (1908) ("[T]he claims measure the invention.").

That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class. For instance, it may suffice to give an example (or a few examples) if the specification also discloses "some general quality . . . running through" the class that gives it "a peculiar fitness for the particular purpose." *Incandescent Lamp*, 159 U. S., at 475. In some cases, disclosing that general quality may reliably enable a person skilled in the art to make and use all of what is

claimed, not merely a subset. See *id.*, at 475–476.[1]

Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing. In *Wood*, a patent claimed a process for making bricks by mixing coal dust into clay. 5 How., at 4. The patent included "a general rule" about the proportion of dust and clay to use and offered two alternative proportions "where the clay has some peculiarity." *Id.*, at 5. The Court upheld the claim, recognizing that "some small difference in the proportions must occasionally be required" given the varieties of clay. *Ibid.* Similarly, in *Minerals Separation*, the Court dismissed a challenge to a claimed process for separating metal from mineral ores. 242 U. S., at 270. The record showed that "preliminary tests" were required to adapt the process to any particular ore. *Ibid.* Once more, the Court explained that "the certainty which the law requires in patents is not greater than is reasonable." *Ibid.* And because the "composition of ores varies infinitely," it was "impossible to specify in a patent the precise treatment which would be most successful and economical in each case." *Id.*, at 271.[2]

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[1] See also *Béné* v. *Jeantet*, 129 U. S. 683, 684–686 (1889) (rejecting claim to method of shrinking coarse hair because the specification failed to give "one skilled in chemistry such an idea of the particular kinds and character of the chemicals, or combination of chemicals, with the relative proportions of each, as would enable him to use the invention without having to resort to experiments of his own to discover those ingredients"); *Corona Cord Tire Co.* v. *Dovan Chemical Corp.*, 276 U. S. 358, 385 (1928) (rejecting claims to process of treating rubber with "'a disubstituted guanidine'" because "between fifty and one hundred substances" fit that description and the specification did not disclose "any general quality common to disubstituted guanidines which makes them all effective").

[2] See also, *e.g., Ives* v. *Hamilton*, 92 U. S. 426, 429, 432 (1876) (upholding claim "for an improvement in sawmills" based on "curved guides at the upper end of the saw," even though the specification did not "stat[e] the nature of the curve," because a "good mechanic acquainted with the construction of sawmills, and having the patent and diagram before him,

Decisions such as *Wood* and *Minerals Separation* establish that a specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art. See *Minerals Separation*, 242 U. S., at 270–271; see also *Mowry* v. *Whitney*, 14 Wall. 620, 644 (1872) ("[T]he definiteness of a specification must vary with the nature of its subject. Addressed as it is to those skilled in the art, it may leave something to their skill in applying the invention."). But in allowing that much tolerance, courts cannot detract from the basic statutory requirement that a patent's specification describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to "make and use" the invention. §112(a). Judges may no more subtract from the requirements for obtaining a patent that Congress has prescribed than they may add to them. See *Bilski* v. *Kappos*, 561 U. S. 593, 602–603, 612 (2010).

III

With these principles in mind, we return to claims 19 and 29 of the '165 patent and claim 7 of the '741 patent. In doing so, we do not doubt that Amgen's specification enables the 26 exemplary antibodies it identifies by their amino acid sequences. Even Sanofi concedes that description is enough to allow a person skilled in the art to make and use those embodiments. See Tr. of Oral Arg. 68. But the claims before us sweep much broader than those 26 antibodies. And we agree with the lower courts that Amgen has failed to enable all that it has claimed, even allowing for a reasonable degree of experimentation.

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would have no difficulty in adopting the improvement, and making suitable curves"); *Tilghman* v. *Proctor*, 102 U. S. 707, 732–733 (1881) (upholding claim for process of separating fats and oils even though the specification "suggests a trial . . . with different degrees of heat so as to ascertain that which is best for each particular kind of fat").

While the technology at the heart of this case is thoroughly modern, from the law's perspective Amgen's claims bear more than a passing resemblance to those this Court faced long ago in *Morse*, *Incandescent Lamp*, and *Holland Furniture*. Amgen seeks to monopolize an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors. The record reflects that this class of antibodies does not include just the 26 that Amgen has described by their amino acid sequences, but a "vast" number of additional antibodies that it has not. 987 F. 3d, at 1085, 1088; see 2019 WL 4058927, *8 ("at least millions of candidates"); see also Tr. of Oral Arg. 52–53. Much as Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering, Amgen seeks to claim "sovereignty over [an] entire kingdom" of antibodies. *Incandescent Lamp*, 159 U. S., at 476.

That poses Amgen with a challenge. For if our cases teach anything, it is that the more a party claims, the broader the monopoly it demands, the more it must enable. That holds true whether the case involves telegraphs devised in the 19th century, glues invented in the 20th, or antibody treatments developed in the 21st. To be fair, Amgen does not dispute this much. It freely admits that it seeks to claim for itself an entire universe of antibodies. Still, it says, its broad claims are enabled because scientists can make and use every undisclosed but functional antibody if they simply follow the company's "roadmap" or its proposal for "conservative substitution."

We cannot agree. These two approaches amount to little more than two research assignments. The first merely describes step-by-step Amgen's own trial-and-error method for finding functional antibodies—calling on scientists to

create a wide range of candidate antibodies and then screen each to see which happen to bind to PCSK9 in the right place and block it from binding to LDL receptors. See Part I–B, *supra*; 987 F. 3d, at 1088; 2019 WL 4058927, *10–*13. The second isn't much different. It requires scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too—an uncertain prospect given the state of the art. See Parts I–A, I–B, *supra*; 987 F. 3d, at 1088; 2019 WL 4058927, *10–*13. Whether methods like a "roadmap" or "conservative substitution" might suffice to enable other claims in other patents—perhaps because, as this Court suggested in *Incandescent Lamp*, the inventor identifies a quality common to every functional embodiment, *supra*, at 13—they do not here. They leave a scientist about where Sawyer and Man left Edison: forced to engage in "painstaking experimentation" to see what works. 159 U. S., at 475. That is not enablement. More nearly, it is "a hunting license." *Brenner* v. *Manson*, 383 U. S. 519, 536 (1966).

Think about it this way. "Imagine a combination lock with 100 tumblers, each of which can be set to 20 different positions." Brief for Intellectual Property Law Professors and Scholars as *Amici Curiae* 20. "Through trial and error, imagine that an inventor finds and discloses 26 different successful lock combinations." *Ibid.* But imagine, too, "that the inventor tries to claim much more, namely all successful combinations," while instructing others "to randomly try a large set of combinations and then record the successful ones." *Id.*, at 21. Sure enough, that kind of "roadmap" would produce functional combinations. *Ibid.* But it would not enable others to make and use functional combinations; it would instead leave them to "random trial-and-error discovery." *Ibid.* Like many analogies, this one may oversimplify a bit, but it captures the gist of the problem.

Failing in its primary argument that it has enabled all of the antibodies it claims, Amgen tries a few alternative lines

of attack. First, it suggests that the Federal Circuit erred by applying an enablement test unmoored from the statutory text. As Amgen sees it, that court conflated the question whether an invention is enabled with the question how long may it take a person skilled in the art to make every embodiment within a broad claim. See Brief for Petitioners 24–29; see also *id.*, at 2, 19–20, 30–36. We do not see it that way. While we agree with Amgen that enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim, we are not so sure the Federal Circuit thought otherwise. That court went out of its way to say that it "do[es] not hold that the effort required to exhaust a genus is dispositive." 987 F. 3d, at 1088 (emphasis deleted). Instead, the court stressed, the problem it saw is the same problem we see: Amgen offers persons skilled in the art little more than advice to engage in "trial and error." *Ibid.* (internal quotation marks omitted). In any event, we review judgments of the lower courts, not statements in their opinions. See *Black* v. *Cutter Laboratories*, 351 U. S. 292, 297 (1956).

Taking a similar tack, Amgen next argues that the Federal Circuit erroneously "raise[d] the bar" for enablement of claims that, like Amgen's, encompass an entire "genus" of embodiments defined by their function. Brief for Petitioners 25 (internal quotation marks omitted). This is impermissible, Amgen argues, because the Patent Act "provides a single, universal enablement standard for all invention[s]." *Ibid.* (internal quotation marks omitted). Here, too, we agree with Amgen in principle: There is one statutory enablement standard. But, once more, we do not understand the Federal Circuit to have thought differently. Instead, we understand that court to have recognized only that the more a party claims for itself the more it must enable. As we have seen, that much is entirely consistent with Congress's directive and this Court's precedents.

Finally, Amgen warns that an affirmance risks "destroy[ing] incentives for breakthrough inventions." *Id.,* at 38. But striking the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress. Since 1790, Congress has included an enablement mandate as one feature among many designed to achieve the balance it wishes. Our only duty in this case lies in applying that mandate faithfully.

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Section 112 of the Patent Act reflects Congress's judgment that if an inventor claims a lot, but enables only a little, the public does not receive its benefit of the bargain. For more than 150 years, this Court has enforced the statutory enablement requirement according to its terms. If the Court had not done so in *Incandescent Lamp*, it might have been writing decisions like *Holland Furniture* in the dark. Today's case may involve a new technology, but the legal principle is the same. The judgment is

Affirmed.